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December 6, 2006

United States District Court
District of Massachusetts
Donahue Federal Building
595 Main Street
Worcester, Massachusetts 01608

Attn: Honorable F. Dennis Saylor IV

Re: Inner-Tite Corp vs. DeWalch Technologies, Inc.
D.Mass. Civil Action No. 04-40219 FDS
Our File No. INNER.7797

Dear Judge Saylor:

In connection with the motion for summary judgment filed by plaintiff [docket item 38] and the hearing on July 26, 2006, plaintiff encloses for the Court's information and convenience a copy of a recent decision of the Court of Appeals for the Federal Circuit that bears on certain issues before the court in the above motion, namely the doctrine of equivalents and the claim vitiation doctrine.

Thank you for your time and attention to this matter.

Sincerely,



William E. Hilton

WEH/mhc
Enclosure
cc: w/enc.

Denise W. DeFranco, Esq.
Peter E. Mims, Esq.

United States Court of Appeals for the Federal Circuit

05-1311, -1335

DEPUY SPINE, INC. (formerly known as Depuy Acromed, Inc.)
and BIEDERMANN MOTECH GMBH,

Plaintiffs-Appellants,

v.

MEDTRONIC SOFAMOR DANEK, INC.
(formerly known as Sofamor Danek Group, Inc.)
and MEDTRONIC SOFAMOR DANEK USA, INC.,

Defendants-Cross Appellants.

DECIDED: November 20, 2006

Before NEWMAN, LINN, and PROST, Circuit Judges.

LINN, Circuit Judge.

DePuy Spine, Inc. (formerly DePuy AcroMed, Inc.) and Biedermann Motech GmbH (collectively "DePuy") appeal from grants of summary judgment that the Vertex® and bottom-loaded types of devices marketed by Medtronic Sofamor Danek, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "Medtronic") do not infringe U.S. Patent No. 5,207,678 ('678 patent). DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Apr. 14, 2003) ("All Models Order"); DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Feb. 24, 2004) ("Vertex Order"). Medtronic cross-appeals from the denial of its motion for judgment as

a matter of law (JMOL) and the final judgment entered after a jury verdict finding that Medtronic's MAS polyaxial pedicle screws infringe the '678 patent by equivalents and awarding lost profit damages. DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Feb. 10, 2005). We conclude that the district court erred in granting summary judgment of non-infringement on the Vertex® model. We also conclude that district court's judgment of non-infringement for the bottom-loaded screw devices was proper and that it correctly determined that Medtronic was not entitled to judgment as a matter of law on the issues of non-infringement or lost profit damages for the MAS polyaxial pedicle screws and correctly entered judgment of infringement as to the MAS device. Thus, we affirm-in-part, reverse-in-part, and remand.

BACKGROUND

DePuy Spine and Biedermann Motech are the exclusive licensee and assignee, respectively, of the '678 patent. The '678 patent involves pedicle screws and receiver members used in spinal surgeries. Pedicle screws are implanted into the vertebrae during surgery. The head of each pedicle screw is connected to a receiver portion, and a threaded rod connects the receiver portions of several screws. Together, the screws, receiver portions, and rods are used to stabilize spinal column segments.

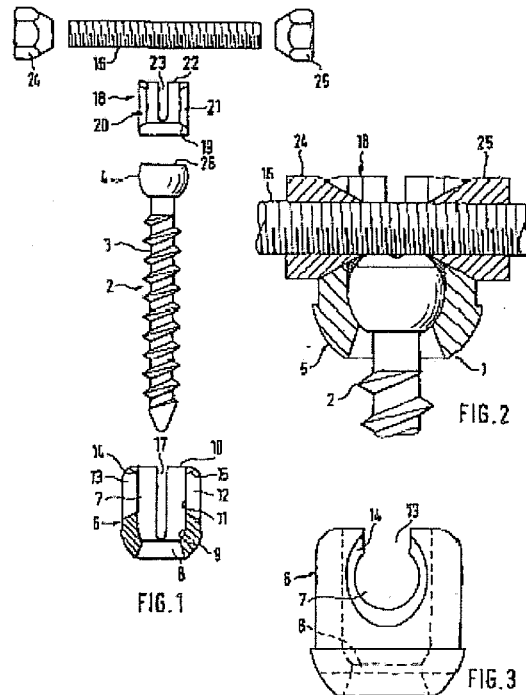
In the prior art, it was difficult for surgeons to rigidly install the screws into adjacent vertebrae in the exact positions needed to properly align the receiver portions to receive the threaded rod. To overcome this problem, improved structures were developed that used a spherical screw head and a halved receiver portion with a spherical cavity. This allowed pivoted movement of the receiver portion much like a

ball-and-socket joint, but required precise machining of matching spherical portions of different sizes and therefore resulted in high stocking costs.

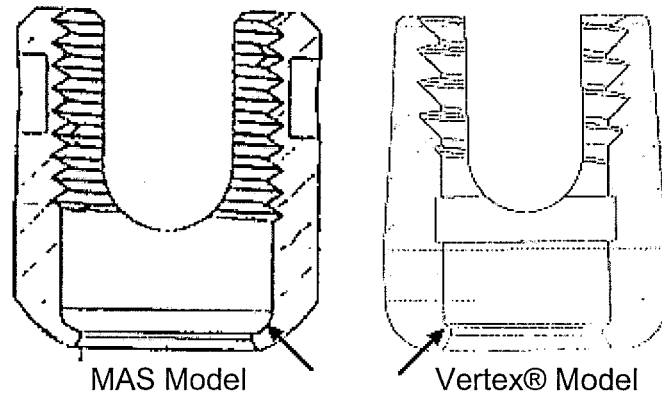
The '678 patent attempts to reduce stocking costs for pedicle screws by using a uniform receiver portion that can be placed on different sizes of spherical heads. Claim 1 is representative of all claims on appeal:

1. Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod 916) [sic:(16)], a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough and an inner hollow spherically-shaped portion (9) for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow spherically-shaped portion (9).

'678 patent, col. 4, ll. 9-24 (emphasis added). The highlighted limitations are at issue on appeal and are termed, respectively, as the "bore," "spherically-shaped," "opening," "compression member," and "pressed against" limitations. The invention is illustrated in figures 1 through 3 of the '678 patent, which are reproduced below:



On January 26, 2001, DePuy filed suit against Medtronic asserting infringement of the '678 patent based on Medtronic's MAS, Vertex®, M8, M10, and Sextant models of polyaxial pedicle screws. The MAS and Vertex® models are assembled by placing the screw through a top opening in the receiver member and then securing the top with a crown. In the Vertex® model, the interior portion of the receiver member adjacent to the screw head is of an approximately conical shape; the same area in the MAS model is shaped like a portion of a toroid. The receiver portions for the MAS and Vertex® models are depicted below, with arrows indicating the relevant conical and toroidal portions.



The M8, M10, and Sextant models (“the bottom-loaded screw models”) are assembled by first inserting the crown and screw head into the bottom of the receiver member and then inserting a “snap ring.” The snap ring in the bottom-loaded screw models retains the screw head in a manner similar to how the conical or toroidal areas in the MAS and Vertex® models retain the screw head. In the bottom-loaded screw models, the screw head is too large to pass through the opening at the top of the receiver member.

Medtronic filed three motions seeking summary judgment of non-infringement in January 2003. The first motion asserted that all models lacked the “compression member” limitation, and the second motion asserted that the Vertex® and MAS models lacked the “spherically-shaped” limitation. Both motions were denied. All Models Order, slip op. at 1. The third motion asserted that the bottom-loaded screw models did not possess either the “bore” or “opening” limitations. The district court granted the third motion, concluding that the bottom-loaded screw models lacked the “bore” limitation literally and that the doctrine of equivalents could not be applied without vitiating that limitation. Id., slip op. at 2-3.

The court then conducted a hearing on claim construction and construed two terms at issue in this appeal. The court’s construction of those terms is contained in a

Memorandum Opinion and Order dated October 27, 2003. DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Oct. 27, 2003) (“Claim Construction Order”). The court construed the “spherically-shaped” limitation to mean “approximately spherical, such as a globe or basketball.” Id., slip op. at 17. The court also construed the “compression member” limitation and held that it was not a means-plus-function claim limitation; instead, it construed that limitation “to require an intermediate piece (or member) that applies compression force to the head of the screw.” Id.

Based on the court’s construction of the “spherically-shaped” limitation, Medtronic filed a motion for summary judgment of non-infringement for the Vertex® model. Vertex Order, slip op. at 1. The court concluded that the Vertex® model did not literally infringe the ’678 patent because the inner hollow space of the receiver member had a conical shape that was not approximately spherical. Id., slip op. at 2. The court also concluded that the Vertex® model did not infringe under the doctrine of equivalents. Id., slip op. at 3. Citing Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998), the court held that under the “all elements” rule, it could not find a conical shape to be equivalent to a spherical shape without reading the limitation out of the claim. Id., slip op. at 4. The court also found that the Vertex® model did not do “substantially the same thing” as the device in the ’678 patent because the screw head contacts an edge of the receiver member rather than a larger area. Id., slip op. at 5.

The case proceeded to a jury trial on the MAS model. The jury verdict found that the MAS model infringed the ’678 patent under the doctrine of equivalents and awarded lost profits and reasonable royalty damages. Medtronic moved for judgment as a matter

of law that the MAS model did not infringe under the doctrine of equivalents and that DePuy was not entitled to lost profit damages; both motions were denied.

On appeal, DePuy challenges the court's finding that no issue of material fact exists as to whether the bottom-loaded screw and Vertex® models infringe the '678 patent and the court's application of the "all elements" rule. On cross-appeal, Medtronic challenges the court's construction of the "compression member" limitation and the court's denial of its motions for JMOL. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

This court reviews a district court's grant of summary judgment of non-infringement de novo. Hilgraeve Corp. v. McAfee Assocs., Inc., 224 F.3d 1349, 1352 (Fed. Cir. 2000). Summary judgment is proper only if there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

Claim construction is an issue of law, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), that we review de novo. See Phillips v. AWH Corp., 415 F.3d 1303, 1328 (Fed. Cir. 2005) (en banc); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Infringement, whether literal or under the doctrine of equivalents, is a question of fact. Ferguson Beauregard v. Mega Sys., Inc., 350 F.3d 1327, 1338 (Fed. Cir. 2003). The determination of infringement under the doctrine of equivalents is limited by two primary legal doctrines, prosecution history estoppel and the "all elements" rule, the

applications of which are questions of law. Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1378 (Fed. Cir. 2005).

"We review the district court's denial of a motion for JMOL without deference, applying the same standard employed by the district court." Honeywell, Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1139 (Fed. Cir. 2004) (*en banc*). Federal Rule of Civil Procedure 50(a)(1) provides that a court may grant a motion for JMOL only where "there is no legally sufficient evidentiary basis for a reasonable jury to find for [the non-movant]." Fed. R. Civ. P. 50(a)(1).

"Whether lost profits are legally compensable in a particular situation is a question of law that we review *de novo*." Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1311 (Fed. Cir. 2004).

Interpretation of contract terms is a matter not unique to our exclusive jurisdiction and is therefore reviewed under regional circuit law. See Sun Studs, Inc. v. Applied Theory Assocs., Inc., 772 F.2d 1557, 1561 (Fed. Cir. 1985). The First Circuit treats interpretation of contract terms as a legal question reviewed *de novo*, unless there is such ambiguity in the language as to create a question of fact. Liberty Mut. Ins. Co. v. Greenwich Ins. Co., 417 F.3d 193, 196-97 (1st Cir. 2005). Whether ambiguity exists is considered a question of law. *Id.*

II. Vertex® Model

DePuy argues that the district court improperly granted summary judgment of non-infringement on the Vertex® model because a genuine issue of material fact exists on both literal infringement and infringement under the doctrine of equivalents. With

respect to the doctrine of equivalents, DePuy argues that the court erred in applying both the “all elements” rule and the function-way-result test.

Medtronic counters that the receiver member of the Vertex® device has a conically-shaped hollow portion, rather than a spherically-shaped portion, and therefore does not literally infringe. Medtronic also counters that the court properly applied the relevant law in examining infringement by equivalents. Alternatively, Medtronic counters that even if a “spherically-shaped” equivalent is present in the Vertex® model, the Vertex® model does not meet the “pressed against” limitation because the screw head rests against an edge of the equivalent and not against the actual spherically-shaped portion equivalent. We will begin our analysis with Medtronic’s alternative argument.

A. “Spherically-Shaped” and “Pressed Against”

Claim 1 recites that the screw “head is pressed against the hollow spherically-shaped portion.” The court construed “spherically-shaped” to mean “approximately spherical, such as a globe or a basketball.” The parties do not dispute this construction on appeal. The parties dispute, however, whether the “pressed against” limitation requires that the screw head engage the entire spherically-shaped portion or whether it is enough that the head engage just the “edge” of the spherically-shaped portion.

In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence. See Phillips, 415 F.3d at 1312-17. First, the claim language does not indicate that “hollow spherically-shaped portion” must be limited so as not to include the edge of that portion, nor does it indicate how

much of the hollow spherically-shaped portion must be “pressed against” the screw head. Claim 4, which depends from claim 1, requires that “the radii of the hollow spherically-shaped portions (9, 19) and of the spherically-shaped screw head (4) [be] substantially equal.” ’678 patent, col. 4, ll. 37-40. That implies that independent claim 1 must be broad enough to read on a device with components of unequal radii that nonetheless are pressed against each other. If the screw head has a smaller radius than the hollow spherically-shaped portion, the only part of the spherically-shaped portion against which the screw head would be pressed would be the edge of the hollow spherically-shaped portion.

Second, the specification does not indicate that the “hollow spherically-shaped portion” must be limited to exclude the edge of that portion or that “pressed against” requires a certain amount of contact between the spherically-shaped portion and the screw head. In the absence of a stated reason to exclude the edge, it would ordinarily and customarily be understood that the referenced portion includes any and all parts of the structure. Similarly, in the absence of a stated reason to require a certain amount of contact, it would ordinarily and customarily be understood that the referenced portion is pressed against a screw head when any amount of that portion presses against the screw head. Figures 1 and 2 of the ’678 patent depict hollow spherically-shaped portion 9 in crosshatching that appears to include the edge of the portion. The corresponding description of that portion does not exclude the edge, noting that “[a] portion 9 in the form of a hollow spherical segment is provided in the interior immediately adjacent to the bore.” ’678 patent, col. 2, ll. 21-23. That description indicates that the relevant portion extends all the way to the bore, which necessarily implies that it includes the

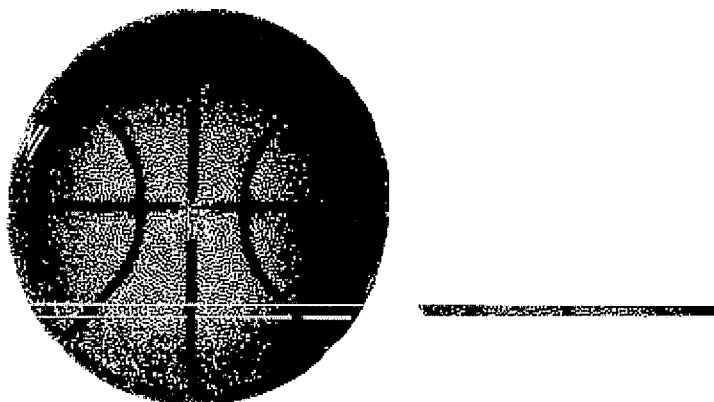
edge. Further, the description does not indicate how much of the spherically-shaped portion presses against the screw head; rather, it notes only that there is “contact” between the components. Id., col. 2, ll. 33-34. The prosecution history provides no further guidance.

For the foregoing reasons, we find Medtronic’s argument unpersuasive, and we conclude that “hollow spherically-shaped portion” includes the edge of that portion and that the screw head is “pressed against” the “hollow spherically-shaped portion” if it presses against all or any part of that portion—including the edge.

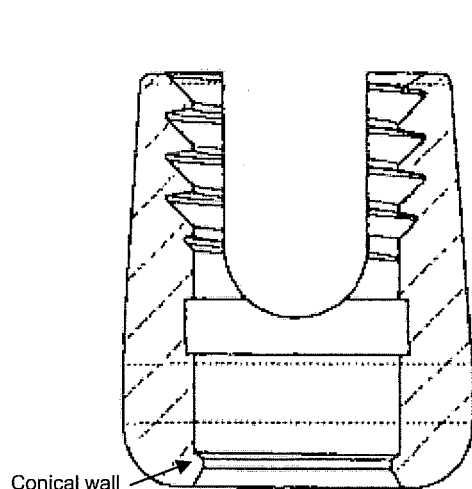
B. Conical Walls

The district court found that there was not a genuine issue of material fact as to literal infringement because the shape of the inner hollow space in the Vertex® model is conical, with “angular rather than spherical” walls. Vertex Order, slip op. at 2-3. The court also found that even if a portion of the shape is spherical, that spherically-shaped portion does not contact the head of the screw. Id., slip op. at 3.

On appeal, DePuy points to two comparisons as evincing a question of fact regarding a spherically-shaped portion in the Vertex® model. First, DePuy points to pictures of a basketball and a selected portion of the basketball, which DePuy submitted as exhibits before the district court. DePuy argues that the picture of the selected portion demonstrates that a thin slice of a sphere creates a profile that appears conical. Depictions of those exhibits are shown below:



Second, DePuy points to a comparison of a cross section of the Vertex® model and Figure 3 of the '678 patent. That comparison is shown in the following figures, with arrows added to indicate the relevant conical and spherical walls:



Vertex® Model

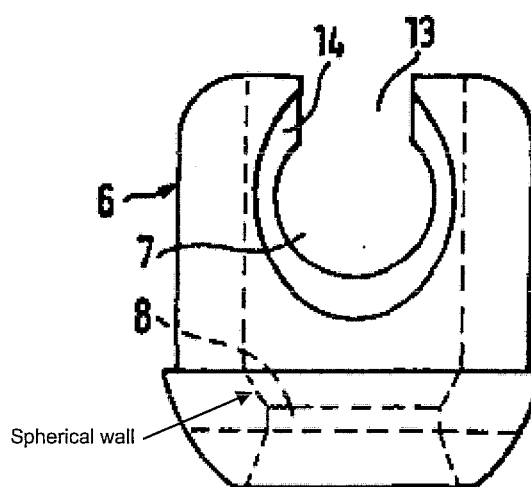


Figure 3 of the '678 Patent

DePuy argues that, like the selected portion of the basketball, the Vertex® model could be viewed as possessing a spherically-shaped portion that appears conical in profile.

Although these comparisons do highlight that at varying degrees of magnification or abstraction a curved surface can appear angular, they do not create a genuine issue of material fact as to whether the Vertex® model possesses the “spherically-shaped” limitation. DePuy points to no evidence that specifically identifies a region in the

Vertex® model as “spherical.” Indeed, DePuy’s expert acknowledged that the engineering drawing of the Vertex® model shows a “conically-shaped” hollow portion, and that a photomicrograph of the Vertex® receiver shows a ledge—not a sphere—even if it contains some rounding at the edges. At best, these declarations identify a conical or ledge structure; they do not constitute evidence of a portion that meets the literal terms “approximately spherical, such as a globe or a basketball.” Therefore, the district court did not err in concluding that there was no genuine issue of material fact as to literal infringement.

C. Doctrine of Equivalents

The district court determined that it “cannot find that the cylindrical-conical shape of [the Vertex® model’s] receiver member is equivalent to the spherically-shaped portion disclosed in the ’678 patent.” Vertex Order, slip op. at 4. The court first applied the “all elements” rule and concluded that, as in Tronzo, treating a conical shape as the equivalent of a spherical shape would vitiate the “spherically-shaped” limitation. Id. The court also applied the function-way-result test and determined that, because the screw head in the Vertex® model “is merely pressed against an edge or lip on the receiver member,” the Vertex® model does not do “substantially the same thing” as the device in the ’678 patent. Id., slip op. at 5.

Under the doctrine of equivalents, “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” Warner-Jenkinson Co. v. Hilton Davis

Chem. Co., 520 U.S. 17, 21 (1997) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)). The doctrine recognizes that

[t]he language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty. If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 731 (2002); Graver Tank, 339 U.S. at 605 (“[T]o permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing.”).

One limit on the doctrine of equivalents is the “all elements” rule. The “all elements” rule attempts to balance the doctrine of equivalents with the basic patent law principle that claim language defines the scope of an invention and every limitation is material.

Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Warner-Jenkinson, 520 U.S. at 29. Thus, as a practical matter, the “all elements” rule informs a doctrine of equivalents analysis by requiring that equivalence be assessed on a limitation-by-limitation basis, rather than from the perspective of the invention as a whole, and that no limitation be read completely out of the claim. Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005).

In Warner-Jenkinson, the Supreme Court provided guidance for determining when resort to the doctrine of equivalents is precluded as a matter of law. First, the Court noted that “[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment.” Warner-Jenkinson, 520 U.S. at 39 n.8 (citing Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). Second, the Court noted that “under the particular facts of a case, . . . if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court.” Id. at 39 n.8.

Informed by this guidance, we have held that in certain instances, the “all elements” rule forecloses resort to the doctrine of equivalents because, on the facts or theories presented in a case, a limitation would be read completely out of the claim—i.e., the limitation would be effectively removed or “vitiating.” For instance, we have concluded that in some cases, the evidence was such that no reasonable jury could determine a proffered equivalent to be insubstantially different from the claimed limitation. See, e.g., Freedman Seating, 420 F.3d at 1361 (holding that a limitation was vitiated in part because the structural difference in the accused device “is not a ‘subtle difference in degree,’ but rather ‘a clear, substantial difference or difference in kind’” (internal citation omitted)); Ethicon, 149 F.3d 1309, 1319 (Fed. Cir. 1998) (holding that the “all elements” rule barred application of the doctrine of equivalents because, on the facts presented, no reasonable jury could find the differences to be insubstantial). We have also concluded that in some cases, the patentee’s theory of equivalence was legally insufficient because, rather than demonstrate an insubstantial difference

between a limitation and an element in the accused device, the theory effectively eliminated a limitation in its entirety. See, e.g., Tronzo, 156 F.3d at 1160 (holding that the patentee's theory of equivalence—that “any shape would be equivalent to the conical limitation”—would write such a limitation out of the claims (emphasis in original)); Forest Labs., Inc. v. Abbot Labs., 239 F.3d 1305, 1313 (Fed. Cir. 2001) (holding that the patentee's theory of equivalence—that a limitation on the percentages of water in a composition was “irrelevant” when compared to the accused composition—vitiates such a limitation). Thus, the “all elements” rule generally is not met—and therefore a claim limitation can be said to be vitiated—if the theory or evidence of equivalence is legally incapable of establishing that the differences between the limitation in the claim and the accused device are insubstantial; i.e., if the theory or evidence is so legally insufficient as to warrant a holding of non-infringement as a matter of law. Warner-Jenkinson, 520 U.S. at 39 n.8; Metro. R.R. Co. v. Moore, 121 U.S. 558, 569 (1887) (“Strictly speaking, evidence is said to be insufficient in law only in those cases where there is a total absence of such proof, either as to its quantity or kind, as in the particular case some rule of law requires as essential to the establishment of the fact.”); see also Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1425-26, 1429-30 (Fed. Cir. 1997).

Our decision in Sage Products, decided shortly after Warner-Jenkinson, illustrates the genesis of such an analysis. For one invention in that case, we held that resort to the doctrine of equivalents was foreclosed because no reasonable jury could find that the differences in the accused device were insubstantial. Sage Products, 126 F.3d at 1423-26. In considering equivalence, we noted the simplicity of the structure,

the specificity and narrowness of the claim, and the foreseeability of variations at the time the claim was filed. Id. at 1425 (“No subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation.”). Because under these particular facts, no reasonable jury could find that the differences in the accused device were insubstantial, we concluded that a finding of infringement by equivalents would effectively remove the relevant limitations from the claim and affirmed the district court’s summary judgment of non-infringement. Id. at 1425-26.

For a second invention at issue in Sage Products, we held that the doctrine of equivalents was foreclosed because the patentee’s theory of infringement was improper. Id. at 1429-30. In considering equivalence for a means-plus-function limitation, we noted that the claimed function included the ability to control access by moving between open and closed positions. Id. at 1428-29. The accused product used a permanently locking lid that could not move back to an open position. Id. at 1427. We noted that the patentee’s theory of equivalence—that a permanently locking lid is equivalent to an openable lid—was unsustainable in that it did not offer a “function equivalent to that expressly recited in the claimed element.” Id. at 1429. Because that theory could not support a conclusion of equivalence regardless of the evidence, we concluded that the theory was legally insufficient, declined to apply the doctrine of equivalents, and affirmed the court’s summary judgment of non-infringement. Id. at 1429-30.

It is important to note that when we have held that the doctrine of equivalents cannot be applied to an accused device because it “vitiates” a claim limitation, it was not to hold that the doctrine is always foreclosed whenever a claim limitation does not literally read on an element of an accused device; such an interpretation of the “all elements” rule would swallow the doctrine of equivalents entirely. See Ethicon, 149 F.3d at 1316-17 (holding that a similar interpretation “would force the All Elements rule to swallow the doctrine of equivalents, reducing the application of the doctrine to nothing more than a repeated analysis of literal infringement” (footnote omitted)). “[A]ny analysis of infringement under the doctrine of equivalents necessarily deals with subject matter that is ‘beyond,’ ‘ignored’ by, and not included in the literal scope of a claim.” Id. at 1317 (emphasis in original). A holding that the doctrine of equivalents cannot be applied to an accused device because it “vitiates” a claim limitation is nothing more than a conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency.

Here, in applying the “all elements” rule, the district court relied solely on Tronzo and concluded that “the cylindrical-conical shape of the [Vertex® model] cannot infringe the ’678 patent without reading out of the claim the express requirement that the screw head be ‘pressed against the hollow, spherically-shaped portion.’” Vertex Order, slip op. at 4 (emphasis added). The court also noted that “permitting the cylindrical-conical shape of the [Vertex® model] to be considered equivalent to the spherical shape required by the ’678 patent vitiates the ’678 patent requirement that the spherically-

shaped head . . . be pressed against an inner, hollow, spherically-shaped portion of the receiver member.” Id., slip op. at 4 n.3 (emphasis added). The district court also determined that this conclusion was supported by the function-way-result test because the conically-shaped portion of the Vertex® model and the “spherically-shaped” limitation of the claim do not “do ‘substantially the same thing.’” Id., slip op. at 5.

We find no support in the present case for the district court’s conclusion that applying the doctrine of equivalents would vitiate or read out the “spherically-shaped” limitation. Our decision in Tronzo is factually distinguishable.¹ In Tronzo, the invention related to artificial hip sockets and the patent at issue was a continuation-in-part. 156 F.3d at 1156-57. The independent claims that were added in the continuation covered a prosthesis socket with no specific shape. Id. at 1157-58. Because the written description only disclosed a conical shape for the prosthesis and characterized other shapes as “prior art” and “inferior” to a conical shape, we held that the independent claims were unsupported by the written description, not entitled to the parent’s filing date, and thus invalid in view of intervening prior art. See id. at 1158-60. The only valid claims at issue in Tronzo were dependent claims that limited the prosthesis body to having “a generally conical outer surface.” The patentee attempted to prove infringement of an accused product with a hemispherical outer surface under the doctrine of equivalents because, “[a]ccording to the expert testimony, any shape would be equivalent to the conical limitation.” Id. at 1160 (emphasis in original). The theory of

¹ As we noted in Optical Disc Corp. v. Del Mar Avionics, “Tronzo does not stand for the proposition that a claim limitation describing a specific shape of a claimed structure cannot be infringed under the doctrine of equivalents by a differently shaped structure.” 208 F.3d 1324, 1337 (Fed. Cir. 2000). Instead, Tronzo is limited to the facts and theories of equivalence presented in that case.

equivalence, therefore, did not identify a specific element of the accused product as an equivalent to the “generally conical” limitation; rather, the patentee argued that any shape would be equivalent to a conical shape, despite clear indications in the written description to the contrary. We concluded that such a theory was insufficient as a matter of law and thus “would write the ‘generally conical outer surface’ limitation out the claims.” Id. (citing Warner-Jenkinson, 520 U.S. at 39 n.8). Accordingly, we reversed the finding of infringement under the doctrine of equivalents. Id.

Here, unlike the patentee in Tronzo, DePuy did not propose that any shape would meet the “spherically-shaped” limitation. Rather, DePuy’s expert presented particularized declarations demonstrating its theory that a specific element of the accused device—the hollow conically-shaped portion of the receiver member—was insubstantially different from the corresponding “spherically-shaped” limitation because it supported the screw head, allowed for flexible movement, and—when the compression member is engaged—creates a rigid lock between the screw head and the receiver. Indeed, the expert expressly identified certain shapes that were different from the accused device but would not be capable of supporting the screw head, allowing flexible movement, and creating a rigid lock when the compression member is engaged. Also, unlike the patent at issue in Tronzo, the written description in the ’678 patent does not label other shapes as “prior art” and “inferior.” Thus, unlike the theory presented in Tronzo, DePuy’s theory of equivalence was not improper.

The district court also erred in concluding that no reasonable jury could find the conically-shaped portion to be an equivalent to the “spherically-shaped” limitation because it does not do “substantially the same thing.” The district court’s conclusion

rested solely on the fact that the screw head in the Vertex® model contacts an edge of the hollow portion as opposed to pressing against a much larger area. Vertex Order, slip op. at 5. As discussed above, properly construed, the “hollow spherically-shaped portion” includes the edge of that portion. Because the screw head in the Vertex® model presses against an edge of a hollow conically-shaped portion argued to be an equivalent of the “spherically-shaped” limitation, a question of fact exists as to whether the difference in the equivalent is substantial.

Because DePuy’s theory of equivalence is not legally insufficient, and because we find that a question of fact exists as to whether the difference between the “spherically-shaped” limitation and the alleged equivalent is substantial, we hold that the district court erred in granting summary judgment of non-infringement under the doctrine of equivalents for the Vertex® model.

III. Bottom-Loaded Screw Models

DePuy argues that the district court erred in granting summary judgment of non-infringement for the bottom-loaded screw models because the court reached its determination without construing the “bore” limitation on which the decision was based. DePuy also argues that, to the extent a de facto construction was used in the court’s analysis, the construction incorrectly added a process limitation to a product claim by construing “passing” to mean that a screw shaft must move through the bore. DePuy argues that “passing” means that the screw shaft is positioned to extend through the bore and does not imply movement. Alternatively, DePuy argues that even if “passing” does imply movement, the screw shaft moves through a snap ring element that meets the “bore” limitation literally or as an equivalent.

Medtronic counters that DePuy's argument that "passing" means "extending" was waived because it was first advanced on a motion for reconsideration and not originally argued in opposition to Medtronic's summary judgment motion. Medtronic also counters that the district court correctly construed the "bore" limitation as requiring a bore that is part of the receiver chamber when a threaded screw shaft moves through it, and that such a construction does not import a process limitation into the claims. In passing, Medtronic asserts that the district court recognized that the bottom-loaded screw models also lacked the "opening" limitation and that this limitation provides a further basis for affirming summary judgment of non-infringement.

Although the district court quoted language from claim 1 of the '678 patent that included the "opening" limitation, it is clear that the court based its conclusion on the "bore" limitation and not the "opening" limitation. See All Models Order, slip op. at 2 ("In particular, the defendant's [bottom-loaded screw models] lack ' . . . the receiver chamber (7) having at one end thereof a bore for passing the threaded shaft portion (3) therethrough.'"). Indeed, the entirety of the infringement analysis was focused on whether the bottom-loaded screw models possessed the "bore" limitation:

It is important to the Court's conclusion that claim 1 requires the bore, through which the threaded shaft of the screw must pass, to be part of the receiver chamber Because Medtronic's [bottom-loaded screw models] do not embody this limitation, they do not literally infringe claim 1. Nor can infringement be found through application of the doctrine of equivalents."

Id., slip op. at 2-3 (citations omitted). Thus, nothing in the district court's summary judgment opinion addresses the "opening" limitation. However, "[w]e sit to review judgments, not opinions." Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540 (Fed. Cir. 1983). The issue was fully argued below and has been raised by Medrad on

appeal; we therefore may address the “opening” limitation. See Glaxo, Inc. v. Torpharm, Inc., 153 F.3d 1366, 1371-72 (Fed. Cir. 1998) (“When a matter comes before an appellate court following summary judgment, the appellate court is free to adopt a ground advanced by the appellee in seeking summary judgment but not adopted by the trial court.”).

The language of claim 1 of the '678 patent claims a receiver member with a bore at one end and an opening “opposite said bore (8) for inserting said screw.” The claim language therefore identifies two clear requirements for the opening: (1) it must be physically located opposite from the bore and (2) it must be “for inserting said screw.” The specification indicates that the opening 10 and hollow cylindrical portion 11 must be of sufficient size to allow the screw head 4 to be inserted into the hollow spherical-segment-shaped portion 9. '678 patent, col. 2, ll. 21-34. Thus, when read in view of the specification, “for inserting said screw” is a functional limitation that requires that the opening be capable of inserting the screw. We therefore construe the “opening” limitation to mean that there must be an opening in the receiver member that is opposite the bore and is capable of inserting the screw.

Medtronic asserts—and DePuy does not contest—that the aperture at the top of the bottom-loaded screw models is not capable of inserting the screw because the diameter of that aperture is smaller than the diameter of the screw head. Medtronic argues that this aperture does not meet the requirements of the “opening” limitation. DePuy appears to counter that the interior space of the receiver member—and not the top aperture—meets the requirement of the “opening” limitation.

We agree with Medtronic. DePuy's theory of infringement argues that the snap ring in the bottom-loaded screw models satisfies the "bore" limitation. Once assembled, the interior space of the receiver member is located next to such bore, not opposite to it. The only aperture that is opposite to the "bore" that DePuy advances is the aperture at the top of the receiver member. However, because it is uncontested that the screw cannot be inserted through that aperture, it cannot meet the functional restriction of the "opening" limitation. Therefore, we conclude as a matter of law that the bottom-loaded screw models do not possess the "opening" limitation and affirm the district court's summary judgment on that basis. Because we affirm summary judgment of no infringement on the basis of the "opening" limitation, we need not address DePuy's arguments with respect to the "bore" limitation.

IV. MAS Model

On cross-appeal, Medtronic argues that the district court erred in denying its motion for JMOL of non-infringement of the MAS model because DePuy failed to offer evidence that the MAS model possessed an equivalent to the "pressed against" limitation that performed substantially the same function, in substantially the same way, to achieve substantially the same result. Specifically, Medtronic acknowledges that DePuy offered function-way-result evidence related to the "hollow spherically-shaped portion" limitation, but argues that no function-way-result evidence was offered demonstrating that pressing against an edge of a hollow portion is the equivalent of pressing against a hollow portion. Medtronic also argues that the court erred in denying its motion because the jury's finding of infringement by equivalence vitiated the "spherically-shaped" limitation. Medtronic argues that here, as in Tronzo, DePuy's

expert offered a theory that “any shape” would meet the “spherically-shaped” limitation, which reads “spherically-shaped” out of the claim.

DePuy counters that it introduced expert testimony that the MAS device possessed an equivalent to the “spherically-shaped” limitation and that the screw head literally presses against that equivalent. DePuy also counters that its expert did not testify to an “any shape will do” theory of equivalence.

Medtronic’s arguments are unpersuasive. First, as discussed in Part II.A, supra, the proper construction of “hollow spherically-shaped portion” includes the edge of that portion. There is no dispute that DePuy presented sufficient evidence that the MAS models possessed the “hollow spherically-shaped portion” or its equivalent. DePuy also presented evidence that the MAS model literally meets the “pressed against” limitation when its expert testified that the screw head presses against an edge of a hollow spherically-shaped portion or the edge of an equivalent. That evidence, together with reasonable inferences in favor of the verdict, make clear that Medtronic was not entitled to judgment as a matter of law on this issue.

Second, DePuy’s expert did not offer an “any shape will do” theory of equivalence similar to the theory offered in Tronzo. In Tronzo, the expert did not identify a specific element in the accused device that was an equivalent to the “generally conical” limitation, but rather testified that any shape would be an equivalent to such a limitation. 156 F.3d at 1160. Here, DePuy’s expert testified that the specific hollow shape of the MAS model was equivalent to the “spherically-shaped” limitation according to the function-way-result test. The “any shape” testimony cited by Medtronic was a reference to earlier deposition testimony on cross-examination and ignores the

witness's explanation on redirect. On redirect, the expert explained that at the deposition, he believed the question was directed to whether the "spherically-shaped" limitation had to be literally present in an accused device. His answer reflected his belief that an equivalent would meet the same limitation. Such an exchange at trial does not constitute an assertion or admission that "any shape" meets the "spherically-shaped" limitation. Because DePuy did not offer a legally insufficient theory of equivalence, Medtronic is not entitled to judgment as a matter of law on this issue.

V. All Accused Devices

Finally, Medtronic argues that the district court failed to properly construe the "compression member" limitation as a means-plus-function limitation, and that under a proper construction, all three accused devices do not infringe. Relying on Mas-Hamilton Group v. Lagard, Inc., 156 F.3d 1206, 1213 (Fed. Cir. 1998), Medtronic argues on cross-appeal that "compression member" is properly construed as a means-plus-function limitation despite the absence of the term "means" and that when the claims are so construed, none of the accused structures infringe. Specifically, Medtronic argues that claim 1 of the '678 patent identifies "compression member" only in terms of function, not structure, and that no credible extrinsic evidence demonstrates that the term has a well-understood structural meaning in the relevant art.

DePuy counters that the absence of the term "means" creates a presumption that "compression member" is not a means-plus-function limitation, that all testifying engineers recognized that the term "compression member" referred to a well-known class of structures, that claim 1 itself imposes certain constraints on the structure of the compression member, and thus the district court's construction was correct.

“Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function.” Phillips, 415 F.3d at 1311 (citing Watts v. XL Sys. Inc., 232 F.3d 877, 880-81 (Fed. Cir. 2000)). “[A] claim term that does not use ‘means’ will trigger the rebuttable presumption that [35 U.S.C.] § 112 ¶ 6 does not apply.” CCS Fitness v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002). This presumption can be rebutted “by showing that the claim element recite[s] a function without reciting sufficient structure for performing that function.” Watts, 232 F.3d at 880. “Our cases make clear, however, that the presumption flowing from the absence of the term ‘means’ is a strong one that is not readily overcome.” Lighting World, Inc. v. Birchwood Lighting, Inc., 382 F.3d 1354, 1358 (Fed. Cir. 2004).

Here, the “compression member” limitation does not use the term “means,” and the presumption against means-plus-function treatment is not overcome. The claims and the specification unmistakably establish that “compression member” refers to particular structure. The claim language demonstrates that the compression member must fit inside the cylindrical opening and be of sufficient size to exert a force on the screw head, which implies structure. ’678 patent, col. 4, ll. 22-24. The specification likewise makes clear that the term “compression member” refers to a particular cylindrical insert and is not simply a general reference to any structure that will perform a particular function. See id., col. 2, l. 58-col. 3, l. 16, col. 3, l. 44-col. 4, l. 6. The prosecution history, while in evidence, provides no further guidance one way or the other. However, dictionary definitions and experts on both sides confirm that “compression member” is an expression that was understood by persons of ordinary skill in the art to describe a kind of structure. See Lighting World, 382 F.3d at 1358

("The task of determining whether the limitation in question should be regarded as a means-plus-function limitation . . . is a question on which evidence from experts may be relevant.").

Moreover, Mas-Hamilton is not applicable here. In that case, no other claim terms attributed structural significance to the elements at issue, and there was no evidence that the term at issue had an understood structural meaning in the art. Mas-Hamilton, 156 F.3d at 1213-15 ("[W]e do not see that the remaining terms in the claim limitation . . . provide any structure necessary to remove this limitation from the ambit of section 112, ¶ 6."); id. at 1215 ("The district court determined that there was no evidence that a 'movable link member' has a well-understood structural meaning in the art."). That is not the case here. Instead, the overall impression of the claims and specification of the '678 patent is that "compression member" implied structure to one of ordinary skill in the art. This is shown by the intrinsic record and confirmed by the extrinsic evidence. Accordingly, we reject Medtronic's argument that the district court erred in not construing "compression member" as a means-plus-function limitation and in not finding non-infringement of all three models on that basis.

VI. JMOL on Lost Profit Damages

Medtronic argues on cross-appeal that the court erred in denying its motion for JMOL on the subject of lost profits because DePuy Spine did not become an exclusive licensee of Biedermann Motech's '678 patent until the 1999 Exclusive License Agreement was entered into on August 31, 1999. Because Biedermann Motech lacked manufacturing and marketing capacity to meet demand, Medtronic argues that neither

party can claim lost profit damages prior to that date and that the jury's judgment awarding damages from before that date should be adjusted.

DePuy counters that determining an exclusive licensee relationship is a factual matter and that substantial evidence supports the jury's finding that an exclusive licensee relationship was created by a 1993 Technology Agreement that became operative with respect to the '678 patent in January 1998. DePuy argues that the 1999 Exclusive License Agreement merely confirmed the rights created by the 1993 Technology Agreement.

Medtronic replies that determining the date when lost profits are legally compensable is a question of law and that the district court determined when DePuy Spine became an exclusive licensee in an Order dated November 18, 2002. Medtronic replies that a 1993 Exclusive License Agreement specifically addressed patent rights whereas the 1993 Technology Agreement did not, and that therefore the 1993 Technology Agreement could not form the basis for an exclusive license under the '678 patent.

Whether DePuy Spine is entitled to lost profits is a question of law. Poly-America, 383 F.3d at 1310-11. DePuy's assertion that determining whether an exclusive license exists is a factual matter is based on Wang Laboratories v. Mitsubishi Electronics, 103 F.3d 1571 (Fed. Cir. 1997). Wang Laboratories dealt with whether an implied license was created as a result of the parties' conduct. Id. at 1578. Though the parties in Wang Laboratories agreed to submit that question to the jury, id., we recognized that the ultimate conclusion was a legal one that was based on underlying findings of fact regarding the parties' conduct and the existence of consideration, id. at

1579-80. Here, the underlying facts are not in dispute. Accordingly, we review this issue de novo.

Medtronic limits its cross-appeal to a challenge of the jury's lost profit award during the period prior to the 1999 Exclusive License Agreement, arguing that (1) DePuy Spine was not an exclusive licensee during the relevant time period, and therefore its lost profits were not recoverable; and (2) Biedermann Motech lacked manufacturing and marketing capacity to meet demand, and therefore it had no basis to recover its own lost profits. Medtronic does not contest that if DePuy Spine was an exclusive licensee during the relevant time period, it is entitled to the lost profits at issue here. See Weiner v. Rollform Inc., 744 F.2d 797, 806-08 (Fed. Cir. 1984) (affirming an award of lost profit damages to a licensee with the exclusive right to sell in the entire United States). We begin our analysis by determining whether DePuy Spine was an exclusive licensee of the '678 patent during the relevant time period.

Medtronic's assertion that the district court ruled on this issue with finality in its November 18, 2002 Order is incorrect. In that Order, the court stated that "[t]he standing of Plaintiff DePuy Acromed, Inc., commenced on August 31, 1999, when Biedermann Motech granted DePuy Acromed an exclusive license to the '678 patent." DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Nov. 18, 2002). To the extent this order reflected the court's initial conclusion, that conclusion was apparently reversed. In denying Medtronic's motion in limine to exclude evidence of lost profits damages before August 31, 1999, the district court found that "Biedermann Motech can recover lost profits [before August 31, 1999] because it was 'closely tied' via a joint venture to the manufacturer, DePuy Acromed, Inc." DePuy

Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Sept. 14, 2004) (citing WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1361 (Fed. Cir. 1999)). In denying Medtronic's renewed motion for JMOL on the subject of lost profit damages, the court noted that DePuy "introduced extensive evidence that DePuy had an exclusive license to the patent in suit as of January 23, 1998." DePuy Acromed, Inc. v. Medtronic Sofamor Danek, Inc., No. 01-10165-EFH (D. Mass. Feb. 15, 2005). Thus, the court ultimately concluded that DePuy was an exclusive licensee as of January 1998.

We must therefore examine the 1993 Technology Agreement to determine if it supports the conclusion that DePuy was an exclusive licensee to the '678 patent under its terms.

Determining whether a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant. The use of the word "exclusive" is not controlling; what matters is the substance of the arrangement. Because patent rights are rights to "exclude others," a licensee is an exclusive licensee only if the patentee has promised, expressly or impliedly, that "others shall be excluded from practicing the invention" within the field covered by the license. Put another way, an exclusive license is "a license to practice the invention accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave."

Textile Prods. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998) (internal citations omitted).

The 1993 Technology Agreement provides that it shall be construed in accordance with Indiana law. Indiana follows the "four corners rule" of contract interpretation in which courts do not look beyond the instrument in question to determine the parties' intent if the terms of the instrument are unambiguous. Schmidt v.

Schmidt, 812 N.E.2d 1074, 1080 (Ind. Ct. App. 2004); see also Univ. of S. Ind. Found. v. Baker, 843 N.E.2d 528, 532 (Ind. 2006). “The terms of a contract are ambiguous only when reasonably intelligent persons would honestly differ as to the meaning of those terms.” Schmidt, 812 N.E.2d at 1080; see also Baker, 843 N.E.2d at 532.

The terms of the 1993 Technology Agreement unambiguously provide an exclusive license to DePuy Spine for all of Biedermann Motech’s current and future knowledge, techniques, processes, data designs, prints, drawings, specifications, procedures and other information relating to the manufacture of any product for use in the treatment of the human spine. In January 1998, Biedermann Motech acquired the ’678 patent, which covers a particular design of pedicle screw for use in the treatment of the human spine. It follows that in 1998, when Biedermann Motech acquired the ’678 patent, it acquired the design of the products covered by that patent as well. That design is a “future” design under the express terms of the 1993 Technology Agreement and provides a basis for the jury’s lost profit award.

The terms of the 1993 and 1999 Exclusive License Agreements do not affect this conclusion. First, the 1993 Exclusive License Agreement is a license between Ort-Med, the licensor, and DePuy Spine, the licensee. Ort-Med never was—nor became—the owner of the ’678 patent. Thus, the 1993 Exclusive License Agreement is not relevant to any determination of rights as between Biedermann Motech and DePuy Spine. Second, the 1999 Exclusive License Agreement was entered into on August 31, 1999; it is thus not relevant to the rights that were created between the parties by the 1993 Technology Agreement entered into on February 4, 1993. Therefore, we conclude that

DePuy was entitled to lost profit damages prior to August 31, 1999, and the court did not err in denying Medtronic's motion for JMOL on this issue.

CONCLUSION

Because the district court erred in construing the scope of the "hollow spherically-shaped portion" in the '678 patent to exclude the edge thereof, and because the court erred in limiting application of the doctrine of equivalents, we reverse the district court's summary judgment of non-infringement under the doctrine of equivalents on the Vertex® model and remand for further proceedings. We affirm the district court's grant of summary judgment of no literal infringement for the Vertex® model.

Because we conclude that the bottom-loaded screw models lack the "opening" limitation as a matter of law, we affirm the district court's grant of summary judgment of non-infringement for the bottom-loaded screw models.

Because the jury verdict finding that the MAS model infringed the '678 patent under the doctrine of equivalents was supported by substantial evidence and because the theory of equivalence was not legally insufficient, we hold that the district did not err in denying Medtronic's motion for JMOL of non-infringement. Because the district court correctly determined that DePuy became an exclusive licensee of the '678 patent prior to August 31, 1999, the district court did not err in denying Medtronic's motion for JMOL to preclude an award of lost profit damages prior to that date. We therefore affirm the jury verdict and damages award on the MAS model.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED.

COSTS

Costs to DePuy.